APPENDIX II: PROPOSED FINDINGS OF FACT

1. Claims 8-21 relate to methods for producing cheese, which comprise:

(1) mixing a partial hydrolysate of milk whey protein with a milk material, to obtain a first mixture;

(2) coagulating said mixture with a milk coagulating enzyme, to obtain a second mixture comprising cheese curd and whey (*see*, page 11, lines 6-16, of the specification).

2. Claims 22-34 relate to methods for producing cheese, which comprise:

(1) mixing a partial hydrolysate of milk whey protein with a milk material, to obtain a first mixture;

(2) treating said first mixture with transglutaminase, to obtain a second mixture; and

(3) coagulating said second mixture with a milk coagulating enzyme, to obtain a mixture comprising cheese curd and whey (*see*, page 11, lines 16-25, of the specification).

3. The presently claimed methods afford a surprisingly enhanced yield of cheese as compared to conventional methods for preparing cheese.

4. The cited references contain no disclosure or suggestion of such methods of preparing cheese.

5. The cited references contain no teaching which would suggest the improved yields afforded by the presently claimed methods.

6. Han et al discloses a process in which a milk product, fortified with whey protein, is first treated with transglutaminase, to effect cross-linking of the whey protein, and then added to another milk product for curding.

7. In the process of Han et al, a cross-linked product of whey protein, not a breakdown or decomposition product (partial hydrolysate) of milk whey protein, is added to the milk.

8. In the method of present Claims 8-21, a ***partial hydrolysate*** of milk whey protein is added to a milk material prior to coagulation.

9. According to Claims 10-12 and 24-26, the partial hydrolysate of milk whey protein may be prepared by treating whey protein with a protease such as trypsin.

10. What is added to the milk in the presently claimed methods is a partial breakdown or decomposition product of whey protein.

11. There is no disclosure of the presently claimed process in Han et al.

12. A key step of the presently claimed methods involves treating the whey protein in a way which is just the opposite to the way described in Han et al.

13. Han et al only discloses the use of a coagulated whey protein and is silent in regard to partially hydrolyzed whey protein.

14. There is nothing in Monti et al which can cure the basic deficiencies of Han et al.

15. There is likewise no teaching in Monti et al which would suggest adding a partial hydrolysate of milk whey protein to a milk material prior to coagulation.

16. Monti et al merely discloses that trypsin digestion is effective for the resolubilization of heat-denatured whey proteins.

17. Monti et al is unconcerned with increasing the amount of whey protein into a cheese product.

18. On page 2 of the Official Action dated February 24, 2003, the position is taken that it would have been obvious to "use the trypsin as taught by" Monti et al in the process of Han et al, because "the use of trypsin serves to increase the solubility of whey protein and consequently makes it easier to incorporate into a cheese product."

19. This conclusion is not supported by the disclosures of the references.

20. There is no teaching in either of the cited references which would suggest that

partial enzymatic digestion of whey proteins would be useful for increasing the incorporation of whey proteins into a cheese product.

21. In fact, the primary reference, Han et al, suggests just the opposite.

22. Han et al discloses that it is by coagulating the whey protein that the incorporation in to a cheese product is increased.

23. The coagulation disclosed in Han et al is essentially just the opposite of the partial enzymatic hydrolysis disclosed in Monti et al.

24. Monti et al is unconcerned with enhancing cheese yield.

25. The skilled artisan would not be motivated to combine the disclosures of Han et al and Monti et al, because to do so would destroy the very heart of the primary reference, Han et al.

26. Specifically, Han et al discloses:

> The process includes ***the significant step*** that a dairy liquid fortified with whey protein is contacted with a transglutaminase to provide a modified dairy liquid containing whey protein products.
>
> Abstract, emphasis added.

* * *

> This invention relates to a method that allows the incorporation of large amounts of whey protein into cheese. ***The method involves the action of a transglutaminase on whey protein to prepare cheese curd incorporating a significant proportion of whey protein.***
>
> Field of the Invention, col. 1, lines 6-10, emphasis added.
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> * * *
>
> The ***principal requirement*** of any transglutaminase employed in the instant invention is that it have the ***cross-linking activity*** discussed above.
>
> Col. 7, lines 18-21, emphasis added.
>
> * * *
>
> The known enzymatic function of transglutaminase is to catalyze the transfer of the γ-carboxamide group of a glutaminyl residue in a protein or peptide to the ε-amino of a lysyl residue of the same or a different protein or peptide. Without wishing to be bound by theory, if such reactions were to occur involving the whey proteins present in the first dairy liquid, glutaminyl-lysyl side chain-side chain crosslinks would form between the protein components present, including crosslinks among and between the whey proteins (i.e., intra- or inter-molecular cross linking).
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> Col. 9, lines 11-20.

27. The point of Han et al is to use a transglutaminase to effect cross-linking of the whey protein to ultimately achieve incorporation of the whey protein into the cheese product.

28. The trypsin partial hydrolysis (bond breaking) of Monti et al is essentially the reverse of the transglutaminase cross-linking (bond making) of Han et al.

29. The use of trypsin in the method of Han et al would completely destroy the heart of this reference.

30. There is nothing in the cited references, even in combination, which would suggest any advantage to be obtained by adding a partial hydrolysate of milk whey protein to a milk material prior to coagulation.

31. It is the surprising discovery of the present inventors that the presently claimed methods for preparing cheese afford dramatic improvements in cheese yield.

32. Table 1, on page 27, of the specification, present the following results:

Test solution: milk (whey decomposed material/TG)	Curd dry material weight (g)	lactose in dry curd (g)	Protein increase (g)
(a) Milk (non-added/non-added)	1.0475	0.318	0 (0%)
(b) Milk (non-added/added)	1.0714	0.306	+0.036 (5%)
(c) Milk (added/non-added)	1.2554	0.360	+0.166 (23%)
(d) Milk (added/added)	1.4331	0.506	+0.198 (27%)

33. The results presented in Table 1 show that addition of the partial hydrolysate of milk whey protein according to the present method, test solutions (c) and (d), affords superior yields as compared to analogous test solutions in which the partial hydrolysate of milk whey

protein was not added, test solutions (a) and (b).

34. There is no teaching in the cited references, even in combination, which would suggest the improved yields for the presently claimed methods, test solutions (c) and (d) in Table 1.

35. Claims 22-34 recite "treating said first mixture with transglutaminase," and, thus, these claims recite the use of tranglutaminase in conjunction with a mixture containing a partial hydrolysate of milk whey protein.

36. The inventors have found that such methods provide an even greater enhancement in the yield of cheese.

37. As shown in the table given above, the use of transglutaminase affords an increase in the yield of cheese of 5% (compare test solutions (a) and (b)). However, the use of transglutaminase in conjunction with a partial hydrolysate of milk whey protein gives a 27% increase in the cheese yield (compare test solutions (a) and (d)).

38. There is nothing in the cited references which would suggest this improved yield.